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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FISHER, ELANA BETH

ART UNIT

PAPER NUMBER

3733

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/575,699	Applicant(s) BIEDERMANN ET AL.	
	Examiner ELANA B. FISHER	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 19-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 April 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/13/2006; 12/27/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of GROUP I, claims 1-18 and newly added claim 23 in the reply filed on March 23, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 19-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 23, 2009.

Drawings

3. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because some of the drawings are done by hand and therefore are not as clear as applicant is capable of providing. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claim 1 recites the limitation "the area or areas which serve to locally reduce rigidity" in fifth line of the claim. There is insufficient antecedent basis for this limitation in the claim.

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6. Claim 4 recites the limitation "the movement function" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 10 recites the limitation "the implant part with material recesses" in the third line of the claim. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 17 recites the limitation "the ends" in the third line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-9, 11-12 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin (U.S. Patent 5,423,816).

Lin discloses an implant (FIG 4) for temporary or permanent introduction into a human or animal body of at least one biocompatible material (Column 2, lines 40-41) with a shape (20, 30) that is oriented to fulfill one or more first functions, wherein the shape has one or more areas (10) in which, as second function, elasticity or mobility is provided, with the implant having material recesses (FIG 3h; FIG 4) in the area or areas (10) which serve to locally reduce rigidity and are provided in addition to the shape (20, 30) caused by the first functions, wherein the implant or at least parts thereof with areas of first and second functions are formed integrally from one material (FIG 4). In the area or

areas (10), the elasticity or movement function is provided in addition to one or more first functions, wherein the area or areas (10) are formed with material recesses as at least one of compression zones, or expansion zones, torsion zones or as articulated joints (FIG 3h; FIG 4). The material recess is formed as at least one of a groove-like helical recess or as an open helical aperture of the wall (FIG 4).

The biocompatible material is of a rigid, especially under the intended conditions of use, flexurally rigid material (Column 2, lines 40-41) and is selected from the group that comprises titanium and alloys thereof as well as plastics (Column 2, lines 40-41). The implant is at least one of a space holder for intervertebral discs with space holder and weight-transfer function as first functions or a connection rod for pedicle screw arrangements with supporting and connection function as first functions (FIG 4). Additionally, the implant has a tube-like body (10) and, on the ends of the tube-like body, has means (60) for connecting to adjacent body parts or other implants or implant parts (FIG 4), with the material recesses in the tube-like body being provided, such that the implant is compressible and extensible in the axial direction and, with reference to the means of connection provided on the ends is bendable about a radial turning and torsionable about an axial rotating axis (FIG 4).

Lin discloses an implant for temporary or permanent introduction into a human or animal body, the implant comprising: a first bone anchoring element (60) for anchoring to a bone or vertebrae; a second bone anchoring element (60) for anchoring to a bone or vertebrae; and a connection element (10) configured to

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connect the first bone anchoring element to the second bone anchoring element, the connection element comprising: a first rigid part (40) configured to connect to the first bone anchoring element, the first rigid part having at least one threaded end (44); a second rigid part (50) configured to connect to the second bone anchoring element, the second rigid part having at least one threaded end (54); a flexible part (10) having a first threaded end (21) and a second threaded end (31) defining a length of the flexible part and comprising a tubular body having a helical recess (10); and wherein the first threaded end of the flexible part is configured to connect to the at least one threaded end of the first rigid part, and wherein the second threaded end of the flexible part is configured to connect to the at least one threaded end of the second rigid part (FIG 4).

11. Claims 1, 10, and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Struder (PCT Publication PCT/CH02/00180).

Struder discloses an implant (FIG 3) for temporary or permanent introduction into a human or animal body of at least one biocompatible material with a shape (5, 6) that is oriented to fulfill one or more first functions, wherein the shape has one or more areas (2) in which, as second function, elasticity or mobility is provided, with the implant having material recesses (FIG 3) in the area or areas which serve to locally reduce rigidity and are provided in addition to the shape caused by the first functions, wherein the implant comprises an implant part (4) of a flexible material, especially of an elastomer, that acts together with the implant part with material recesses to achieve a flexibility such that a definitive rigidity or mobility of the overall implant can be set.

Additionally, the implant has a tube-like body (2) and, on the ends of the tube-like body, has means (5, 6) for connecting to adjacent body parts or other implants or implant parts, with the material recesses in the tube-like body being provided, such that the implant is compressible and extensible in the axial direction and, with reference to the means of connection provided on the ends is bendable about a radial turning axis and torsionable about an axial rotating axis (FIG 3), and further comprising at least one of a sleeve comprising an elastic biocompatible material surrounding the tube-like body a core (4) comprising an elastic biocompatible material, wherein at least one of the sleeve or the core (4) are held by end plates arranged on the tube-like body (FIG 3; FIG 5)

Claim Rejections - 35 USC § 103

12. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin (U.S. Patent 5,423,816).

Lin discloses an implant according to claim 12 above, however fails to disclose the extent of which the tube-like body (10) is extensible or compressible. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the tube-like body be extensible or compressible by 0.5 to 20%, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Furthermore, Lin fails to disclose the extent to which the tube-like body is torsionable/can pivot about the axial axis. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the

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tube-like body be torsionable/can pivot about the axial axis by 0.5 to 10 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELANA B. FISHER whose telephone number is (571)270-3643. The examiner can normally be reached on Monday through Friday from 8:30AM to 5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elana B Fisher/

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733